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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,669	08/16/2001	Masahiro Sakanaka	56238(71526)	4547

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Peter F Corless  
Dike Bronstein Robert & Cushman  
Edwards & Angell  
PO Box 9169  
Boston, MA 02209

EXAMINER

KHARE, DEVESH

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 06/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/913,669

Applicant(s)

SAKANAKA ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**35 U.S.C. 112, second paragraph rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claim 21 is rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is unclear with regard to the phrase "exploring novel active compounds".

**Improper multiple dependent claims rejection**

Claims 11,12 and 24 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall contain a reference, in the alternative only, to more than one claim previously set forth. See MPEP § 608.01(n). Accordingly, the claims 11,12 and 24 are not been further treated on the merits.

**35 U.S.C. 101 reads as follows:**

*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

Claims 25-27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.1967) and *Clinical Products, Ltd. V. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (Neuroscience Research, 28, 191-200 (1997)) in view of Liu (U.S. Patent 4,708,949).

The present invention can be considered in two parts, claims 1-20 and 24 describe a composition comprising ginsenoside (Rb<sub>1</sub>) for the regeneration and/or reconstruction of cerebrovascular networks after cerebral stroke and for the inhibition of secondary nervous tissue degeneration and claims 21-23 describe a method for screening active substances for treating diseases of nervous tissue or spinal cord tissue by using ginsenoside Rb<sub>1</sub> as a leading compound.

Lim et al. entitled "Protection of ischemic hippocampal neurons by ginsenoside Rb<sub>1</sub>, a main ingredient of ginseng root" teaches in the abstract ginsenoside Rb<sub>1</sub> as a neuroprotective agent in the prevention of cerebrovascular diseases. See 'Discussion' on page 196 which describes the study of ginsenoside Rb<sub>1</sub> which have a nerve cell protecting action or cerebral protecting action.

The claims differ from Lim et al. in that they specify the composition comprising ginsenoside (Rb<sub>1</sub>) for treatment of diseases caused by injuries to the nervous tissues or to the spinal cord.

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Liu teaches in abstract the therapeutic compositions composed of four plant extracts: ginsenoside, tetramethyl pyrazine, astragalin and atractylol. This therapeutic composition is highly effective in treating cerebral vascular diseases (also see claims 1-4). In claims 13-17, Liu teaches the method of treating a patient suffering from cerebrovascular disease and impaired neurofunction with a pharmaceutical composition comprising ginsenoside.

Therefore, one of ordinary skill in the art would have found the applicants claimed compositions of ginsenoside Rb<sub>1</sub> and a method of using the said compounds as a lead compound for screening compounds which have a nerve cell protecting action or cerebral protecting action to have been obvious at the time the invention was made having the above references before him because Lim et al. teaches ginsenoside Rb<sub>1</sub> as a neuroprotective agent in the prevention of cerebrovascular diseases and Liu teaches the therapeutic compositions comprising ginsenoside and a method of treating a patient suffering from cerebrovascular disease. The motivation for doing so is provided by Lim et. al. which suggests ginsenoside Rb<sub>1</sub> is a neuroprotective molecule.

#### **State of the Art References**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Pang et al. (U.S. Patent 6,083,932)- discloses the pharmaceutical compositions derived from ginseng and methods of treatment using same.


Meybeck et al. (U.S. Patent 5,747,538)- discloses the pharmaceutical compositions of ginsenoside for promoting collagen synthesis.

Tashiro et al. (U.S. Patent 5,589,182)- discloses the pharmaceutical compositions and method of treating cardio-, cerebrovascular and alzheimer's diseases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (703)308-4532. The official fax phone numbers for the organization where this application or proceeding is assigned is (703)308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

  
Devesh Khare, Ph.D.,JD(2Y).  
Art Unit 1623  
May 30,2002

  
JOHANN RICHTER  
SUPERVISORY PATENT EXAMINER  
GROUP 1200